PRO BRIGHTEN TOOTH WHITENING GEL- hydrogen peroxide gel
Sangleaf Pharm., Co Ltd

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Hydrogen Peroxide 3.00%

Oral Debriding

Aids in the removal of phlegm, mucus, or other secretions associated with occasional sore mouth

Use up to 3 times daily after meals and at bedtime

children under 12 years of age: should be supervised in the use

children under 2 years of age: consult a dentist, doctor

For external use only

The condition persists or gets worse

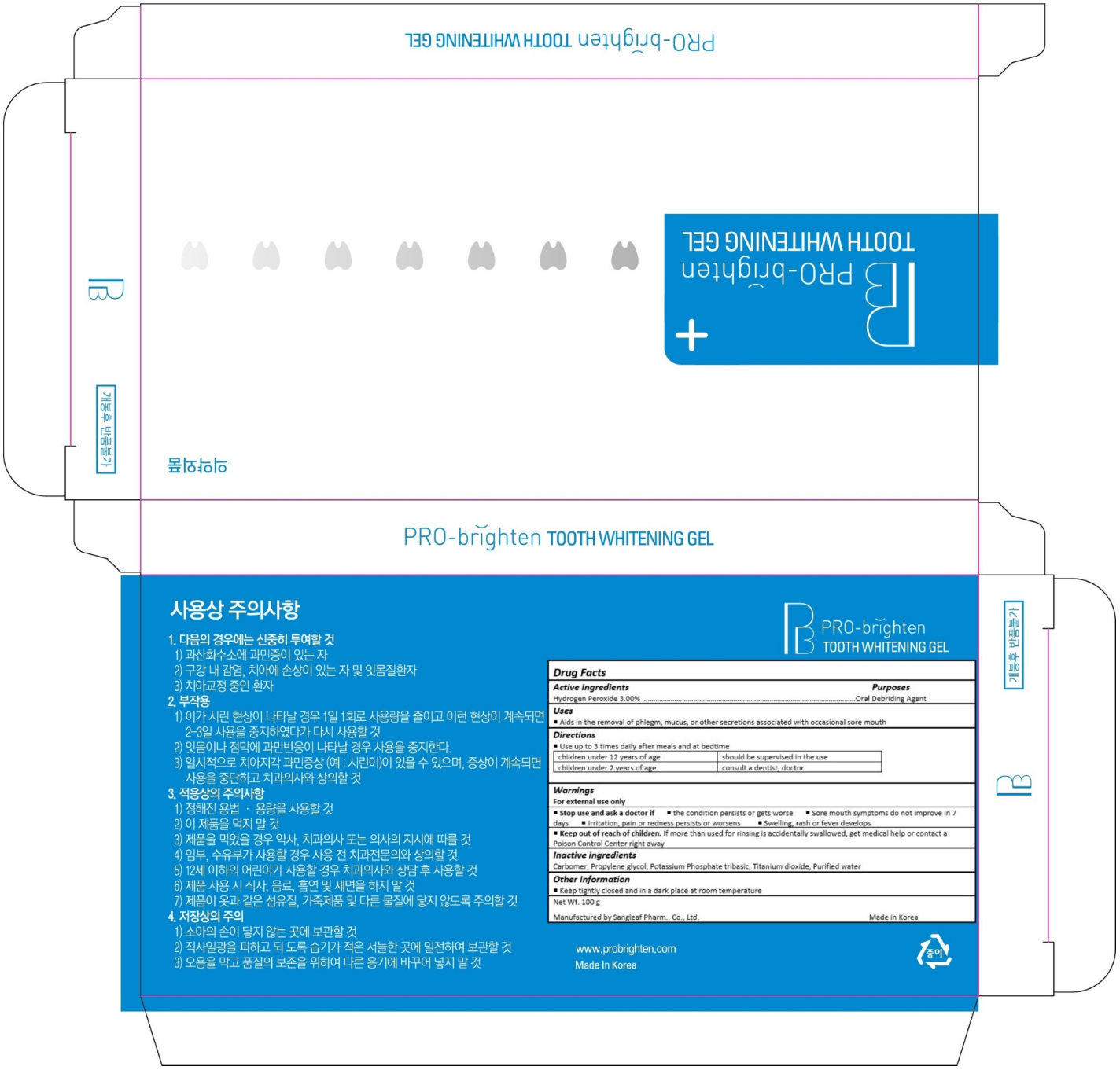
Sore mouth symptoms do not improve in 7 days

Irritation, pain or redness persists or worsens

Swelling, rash or fever develops

Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away

Carbomer, Propylene glycol, Potassium Phosphate tribasic, Titanium dioxide, Purified water



PRO BRIGHTEN TOOTH WHITENING GEL

hydrogen peroxide gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70810-001
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Hydrogen Peroxide (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	Hydrogen Peroxide	3 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POTASSIUM PHOSPHATE, TRIBASIC (UNII: 16D59922JU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70810-001-02	1 in 1 CARTON	07/06/2016	
1	NDC:70810-001-01	100 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	07/06/2016	

Labeler - Sangleaf Pharm., Co Ltd (689847343)

Registrant - Sangleaf Pharm., Co Ltd (689847343)

Establishment

Name	Address	ID/FEI	Business Operations
Sangleaf Pharm., Co Ltd		689847343	manufacture(70810-001)

Revised: 7/2016 Sangleaf Pharm., Co Ltd